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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,168	03/11/2004	Zuhair A. Latif	227763	5111

23460 7590 03/31/2006

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,168	LATIF, ZUHAIR A.	
	Examiner	Art Unit	
	Q. Janice Li, M.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 are pending and under current examination.

Claim Objections

Claim 5 is objected to because a splenocyte is not considered a lymphocyte in the pertinent art (see the definition of On-line Dictionary).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1-4, and 6-8 are rejected under 35 U.S.C. 102(e) as being anticipated by *Forsberg et al* (US 2004/0055025, IDS).

Forsberg et al teach a method of replicating an immune response of a first non-human animal (founder animal) in a second animal (cloned animal), wherein one of the means of replicating is through adoptively transfer of the immune cells of the founder animal to the cloned animal (e.g. claims 1, 8), wherein the animal is selected from the

group consisting of a sheep, a pig, and a cow (claim 4), wherein the immune cells may be lymphocytes (paragraph 0113), and wherein the cloning is somatic cloning or embryonic cell cloning (e.g. paragraph 0077). *Forsberg et al* teach an immune response to an antigen can be produced by subjecting the second animal(s) to the same ***immunization*** strategy as that of the first animal (paragraph 0011), implying the founder animal has been immunized. Thus, *Forsberg et al* anticipate instant claims.

Claims 1-8 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 10/654,723 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

The cited U.S. application claims a common subject matter as instant claims 1-8, and thus anticipates instant claims.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Claims 1-8 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The claims of instant and cited applications are drawn to the same subject matter, yet the cited application has a different inventive entity. It is unclear who is the real inventor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being obvious over *Forsberg et al* (US 2004/0055025), in view of *Wise et al* (J Immunol 1999;162:5592-5600).

The teaching of *Forsberg et al* was detailed *supra*, *Forsberg et al* do not mention that cells of immune system to be transferred may be splenocytes.

Wise et al supplemented *Forsberg et al* by establishing that it was well known in the art splenocytes belong to cells of the immune system, and one can adoptive transfer an immune response from one animal to another by splenocytes.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by *Forsberg et al*, by simply substituting lymphocytes with splenocytes as taught by *Wise et al* with a reasonable expectation of success. Given numerous cell types are known to transfer an immune response, the limitation falls within the bound of optimization. Thus, the claimed

invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-8 of copending Application No. 10/654,723, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, i.e. transferring an immune response from a founder animal to a cloned offspring.

The instant claims differ from the claims of the cited application in that the recitation of "animal" vs. "mammal". However, the term animal fully embraces "mammal".

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Accordingly, the claims as written are obvious variants, and co-extensive.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention are summarized in *In re Wands*, (858 F2d 731,

737, 8 USPQ 2d 1400, 1404, (Fed Cir.1988)). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided. The factors most relevant to this rejection are the nature of the claims relative to the state of the art and the levels of the skilled in the art, and whether sufficient amount of direction or guidance are provided in the specification to enable one of skill in the art to practice the claimed invention.

The claims are drawn to a method of transferring lymphocytes of a founder mammal to a cloned offspring for a time and under conditions sufficient for said cloned mammal to develop *the* immune response of the founder mammal.

As an initial matter, the specification fails to teach how to use the claimed invention. The specification states, "*In this manner, one may create a specific, selective, secondary immune response in an otherwise immunologically naïve mammal*" (Specification, page 1, lines 12-16). Currently, adoptive transfer of lymphocytes are generally used in the art of immunology for a). generating a lymphocyte-mediated disease model in a syngenic or immunodeficient animal; or b). for treating a subject in need of activated lymphocytes, such as in cancer and infectious diseases. Here the second use does not appear to be needed, and the current mammal source satisfies the first use. Thus, it is unclear and the specification fails to teach why it is necessary to go extra miles transferring an immune response to a *cloned* mammal when you can just use the syngenic or immune deficient mammal for creating "a specific, selective, secondary immune response in an otherwise immunologically naïve mammal", and

when such procedure is useful for a specific and real world use, what is the useful benefit one cannot get from current available mammal, and thus, one skilled in the art would not know how to use the invention.

Cloning a mammal is an essential step for practice the invention, and the cloned mammal should be readily available to the public, and be capable of providing *said* immune response of the founder.

To this end, the specification teaches general protocol for cloning and adoptive transfer. However, the specifications fails to teach the efficiency of animal cloning, or reduce to practice transferring any immune cells of a founder mammal to its cloned offspring.

Turning to the state of the art, reproductive cloning is still in its infant stage, and extremely inefficient. Such inefficiency often reflects the real difficulty and challenge in animal cloning. *Yanagimachi* (Mol Cell Endocrinol 2002;187:241-8) teaches around the time of filing that "CLONING EFFICIENCY-AS DETERMINED BY THE PROPORTION OF LIVE OFFSPRING DEVELOPED FROM ALL OOCYTES THAT RECEIVED DONOR CELL NUCLEI-IS LOW REGARDLESS OF THE CELL TYPE (INCLUDING, EMBRYONIC STEM CELLS) AND ANIMAL SPECIES USED. IN ALL ANIMALS EXCEPT OF JAPANESE BLACK BEEF CATTLE, THE VAST MAJORITY OF CLONED EMBRYOS PERISH BEFORE REACHING FULL TERM" (Abstract), and "THUS FAR, CLONED OFFSPRING THAT SURVIVED BIRTH AND REACHED ADULTHOOD WERE THE EXCEPTION RATHER THAN THE RULE (page 243, left column, emphasis added). *Yanagimachi* goes on to teach, "THIS LOW EFFICIENCY OF CLONING SEEMS TO BE DUE LARGELY TO FAULTY EPIGENETIC REPROGRAMMING OF DONOR CELL NUCLEI AFTER TRANSFER INTO RECIPIENT OOCYTES. CLONED EMBRYOS WITH MAJOR EPIGENETIC ERRORS DIE BEFORE OR SOON AFTER IMPLANTATION" (abstract). *Wells et al* (Trends Biotechnol

2003:21:428-32) teach that the continuous loss of clones throughout pregnancy and high mortality during the perinatal period raise serious animal welfare concerns and these losses can mostly be attributed to faulty epigenetic reprogramming of the donor cell genome, resulting in major dysregulation of gene expression (paragraph bridging left & right column in page 1). Clearly, the state of the art has not reach the level of routine experimentation in cloning mammals, and thus the cloned mammal required for practice instant invention do not appear to be readily available for routine adoptive transfer experimentation.

Claims encompass cloning any mammalian species and preferably a horse or a dog. *Wilmut* (Cloning Stem Cell 2003;5:99-100) teaches, "BY THE TIME OF DOLLY'S DEATH IN 2003, CLONES HAD BEEN DERIVED FROM ADULT CELLS OF SEVERN MAMMALIAN SPECIES, BUT THE SAME TECHNIQUES WERE NOT SUCCESSFUL IN SEVEN OTHERS, DESPITE INTENSIVE EFFORTS BY EXPERIENCED RESEARCH TEAMS. THESE INCLUDE RHESUS MONKEY, RAT, DOG, AND HORSE. THIS FAILURE EMPHASIZES THE IMPORTANCE OF DIFFERENTCES BETWEEN SPECIES. THE DIFFERENCE MIGHT BE IN THE MOLECULAR MECHANISMS THAT REGULATE EARLY DEVELOPMENT OR IN ENABLING TECHNIQUES FOR OOCYTE RECOVERY, EMBRYO CULTURE, OR EMBRYO TRANSFER. SUCH DIFFERENCES HAVE ALREADY BEEN IDENTIFIED BETWEEN THE SPECIES FROM WHICH CLONES HAVE BEEN DERIVED". In view of such, the specification fails to provide support for the full scope of the invention.

As to the question whether said cloned mammal is capable of developing *the* immune response of the founder mammal, it depends on the similarity of the founder and the cloned offspring, as well as the type of immune cells being transferred. The specification fails to teach any of the two issues. Turning to the state of the art, it is a

common knowledge in the art that the donor and clone will have the same karyotype or chromosomal number, but the clone and the donor are unlikely to have the same or identical nucleotide sequence because during DNA replication there more likely than not will be some nucleotide changes at least in the "junk" DNA regions or introns, if not some silent mutations in coding regions.

Further, the potential effects of cloning on genetic and epigenetic aspects of cloned offspring remain largely unknown, and remarkable differences between the founder and its clone have been reported in both somatic and embryonic cell nuclear transfer cloning.

Since, except the mouse, the embryonic stem cells for remain mammals recited in claim 2 have yet to be identified, they have to be cloned from somatic cells. A variety of phenotypes and epigenetic alterations have been reported in animals cloned from somatic cells, and the exact nature and consequences of the alterations remain unclear (*Ogura et al*, Cloning and Stem Cells 2002;4:397-405, e.g. the abstract). *Ogura et al* teach even for those mice that were viable at birth and appear to be normal, they died earlier than the genotype-matched controls, "MOST PROBABLY DUE TO SEVERE PNEUMONIA, WHICH INDICATES THAT UNEXPECTED PHENOTYPES CAN APPEAR AS A RESULT OF THE LONG-TERM EFFECTS OF SOMATIC CELL CLONING" (abstract). *Tamashiro et al* (Nat Med 2002;8:262-7) echo such conclusion, and teach, "ALTHOUGH FULL-TERM DEVELOPMENT OF ANIMALS CLONED FROM ADULT SOMATIC CELLS HAS BEEN REPORTED, PROBLEMS IN THE RESULTING PROGENY INDICATE THAT THE CLONING PROCEDURE MAY NOT PRODUCE ANIMALS THAT ARE PHENOTYPICALLY IDENTICAL TO THEIR CELL DONOR" (abstract). *Dr. Wilmut*, a pioneer in animal cloning, teaches "THE MOST STRIKING THING ABOUT THE TECHNIQUES THAT EMERGED DURING DOLLY'S LIFE IS THAT

MAMMALIAN CLONING REMAINS A REPEATABLE, BUT INEFFICIENT PROCEDURE. IT IS STILL TRUE THAT ONLY 1-5% OF RECONSTRUCTED EMBRYOS DEVELOP TO BECOME VIABLE OFFSPRING, REGARDLESS OF VARIATIONS IN SPECIES, CELL TYPE, OR NUCLEAR TRANSFER PROTOCOL. THIS LOW OVERAL SUCCESS RATE IS THE CUMULATIVE EFFECT OF FAILURE AT ALL STAGES OF DEVELOPMENT, INCLUDING AFTER BIRTH. AN EXTRAORDINARY VARIATIY OF ABNORMALITIES HAVE BEEN DESCRIBED IN CLONED FETUSES AND OFFSPRING." And "THIS OUTCOME HAS BEEN ASSOCIATED WITH VERY GREAT VARIATION IN GENE EXPRESSION IN CLONED EMBRYOS, FETUSES, AND OFFSPRING" (Cloning Stem Cells 2003;5:99-10, see mid-section of column 2, page 99, emphasis added). Through pathological study of a group of lambs that were not viable after birth, *Rhind et al* (Nat Biotech 2003;21:744-5) offered an alternative view contrary to the opinion that the majority of cloned animals are 'seemly healthy'. *Rhind et al* teach, "MORE SUBTLE EXPRESSION OF THE DEFECTS COULD BE PRESENT IN SURVIVING CLONES THAT ARE APPARENTLY NORMAL", and "BY REVEALING REPEATED PHENOTYPIC ABNORMALITIES THAT HAVE NOT BEEN PREVIOUSLY RECOGNIZED IN LAMBS GENERATED WITH NUCLEAR TRANSFER TECHNOLOGY, OUR SURVEY REVEALS THE NEED FOR DETAILED PATHOLOGICAL INVESTIGATION OF CLONED ANIMALS THAT FAIL" (paragraph bridging columns 1 & 2, page 745). *Smith and Murphy* (Cloning Stem Cells 2004;6:126-32) point to the underlying reasoning why genetic and epigenetic variations occurred, i.e. the mechanism about how the host cytoplasm and donor nuclei interact to produce a developmentally competent reconstructed embryo is largely unknown. *Smith and Murphy* teach, apart from the major chromosomal anomalies found in developmentally arrested embryos and fetuses, less detrimental rearrangements and/or mutations are likely to go unnoticed in most donor cell karyotypes, which could lead to inheritable anomalies among clones and their offspring. *Smith and Murphy* go on

to teach that the variations may come from the donor nuclear DNA sequence, the mitochondrial DNA from the host oocyte, and epigenetic alterations to the DNA or to the histone packaging proteins.

Even when cloning using ES cells, epigenetic instability may lead to genotype variations. *Humpherys et al* (Science 2001;293:95-7) teach variation in imprinted gene expression was observed in most cloned mice, even in those derived from ES cells of the same subclone. "THESE DATA IMPLY THAT EVEN APPARENTLY NORMAL CLONED ANIMALS MAY HAVE SUBTLE ABNORMALITIES IN GENE EXPRESSION" (abstract).

The claimed invention encompasses cloning primates including human being, *Simerly et al* (Science 2003;300:297) report the molecular obstacles in cloning primates, and concludes, "PRIMATE NUCLEAR TRANSFER APPEARS TO BE CHALLENGED BY STRICTER MOLECULAR REQUIREMENTS FOR MITOTIC SPINDLE ASSEMBLY THAN IN OTHER MAMMALS", AND "WITH CURRENT APPROACHES, NT TO PRODUCE EMBRYONIC STEM CELLS IN NONHUMAN PRIMATES MAY PROVE DIFFICULT—AND REPRODUCTIVE CLONING UNACHIEVABLE". Apparently, it was not and has yet to become routine in the art to obtain genotypically and phenotypically identical mammals, and it has yet to be achieved to clone primates. And thus the cloned mammal, the starting materials for the claimed process do not appear to be readily available to the public.

As to the genotype and phenotype of the immune system of a cloned mammal, the art is silent and the specification fails to teach concerning the state of immune responsiveness and immune compatibility of clones compared to the founder animal. But following the general knowledge detailed *supra*, it is highly unlikely that the

genotypical and phenotypical alterations observed in cloned animals would not apply to the cluster of immune-associated genes, such major and minor MHC class systems. In view of the frequent and great variations between the founder mammal and cloned offspring, it is highly unpredictable and the specification fails to teach whether the offspring could routinely develop an immune response of the founder mammal. Hence it would have required undue experimentation for the skilled in the art to generate a cloned mammal reproducing the immune response of the founder.

While, the intent for citing the references is not to say that a substantially the same immune response can never be achieved in a cloned offspring, the intent is to provide art taught reasoning as to why the instant claims do not appear to be enabled, why the specification fails to teach how to use the invention, and to illustrate the general state of the art in animal cloning and immunology to properly determine whether additional and specific guidance should be provided by the specification.

Therefore, it is incumbent upon applicants to provide sufficient and enabling teachings within the specification for the claimed invention. Although the instant specification provides a brief review of the general protocols for cloning and immunization/adoptive transfer, it is not enabled because it fails to teach how to overcome art known hurdles in reproductive cloning, it fails to provide any insight into the state of the immune system of a cloned animal compared to the founder, or reduce to practice to induce any immune response that is substantially the same as the founder. Here, the general knowledge and levels of skill in the art do not supplement the omitted disclosure.

Therefore, in view of the limited guidance, the lack of predictability of the art and the nature of the claims, one skill in the art could not practice the invention without undue experimentation as it is broadly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 provides a method for cloning a founder mammal, but the claim does not set forth any steps involved in the cloning process. Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity and make clear what subject matter that claims encompass as well as make clear the subject matter from which others would be precluded, *Ex parte Erlich*, 3 USPQ2d 1011 at 6.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730.

The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave T. Nguyen** can be reached on 571-272-0731. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of formal matters can be directed to the patent analyst, **William Phillips**, whose telephone number is (571) 272-0548.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is **(866) 217-9197**. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Q. JANICE LI, M.D.
PRIMARY EXAMINER

Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL
February 24, 2006